

**REMARKS**

Claims 1-34 were previously pending in this Application before entrance of the present Amendment. Claim 1 has been rewritten as a product by process claim incorporating the process of claim 6. Claim 6 has been amended to delete the reference to claim 1. Claims 18 and 32 have been amended to correct typographical errors. New claims 35-42 have been added. Support for new claims 35-38 may be found in original claim 28. Support for new claims 39 and 40 may be found in original claims 6 and 16. Support for new claim 41 may be found on page 5, lines 7-8, of the specification as originally filed. Support for new claim 42 may be found in original claims 1, 6, and 7. Claims 5, 8-11, and 23-27 have been cancelled. Claims 1-4, 6, 7, 12-22, and 28-42 are currently pending and under consideration by the Examiner. No new matter has been added to the present Application by this Amendment.

Each of the rejections levied by the Examiner in the outstanding Office Action is addressed in turn below.

*Claim rejections under 35 U.S.C. § 112*

Claims 28-31 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. More specifically, the Examiner has rejected claims 28-31 on the basis that a compound could be effective against central nervous system, delusional, psychiatric, psychological, or psychotic disorders in general is contrary to our current understanding of how pharmaceuticals work. The Examiner further notes that all attempts to find a pharmaceutical to treat central nervous system, delusional, psychiatric, psychological, and psychotic disorders generally have failed.

Applicant respectfully disagrees and submits herewith the Marketing Authorization for olanzapine, dated July 2, 2001 (included in the Information Disclosure Statement filed herewith; see page 1 of the Commission Decision, which corresponds to page 7 of the Marketing Authorization), which precedes the priority date of the present Application. The Marketing Authorization indicates that olanzapine is indicated for the treatment of patients with schizophrenia, a psychotic disorder (see page 2, section 4.1, of Annex 1, which corresponds to page 11 of the Marketing Authorization). Indeed, at the time of filing the present Application, olanzapine was known to be an antipsychotic agent (*i.e.*, to be effective for treatment of psychotic disorders) (see page 8, section 5.1, of Annex 1,

which corresponds to page 17 of the Marketing Authorization). Furthermore, olanzapine was known to affect the central nervous system (see page 4 of Annex 1, penultimate paragraph, which corresponds to page 13 of the Marketing Authorization). Thus, contrary to the Examiner's assertion, treatment of psychotic disorders is not contrary to our current understanding of how pharmaceuticals work since the enclosed Marketing Authorization indicates that olanzapine is known for the treatment of the psychotic disorder, schizophrenia. Accordingly, Applicant respectfully requests that the rejection of claims 28-31 be withdrawn.

Claims 5 and 23-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Solely to expedite prosecution and without appearing to agree with the Examiner's remarks, Applicant has cancelled claims 5 and 23-27.

*Claim rejections under 35 U.S.C § 102(b)*

Claims 1, 4, 5, 8-13, and 15-34 have been rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Dekemper, International Patent Application Publication No. WO/2003/007912 ("Dekemper"). The Examiner has indicated that claims 6 and 7 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Thus, solely to expedite prosecution and without appearing to agree with the Examiner, independent claim 1 has been rewritten as a product-by-process claim incorporating the process of claim 6. By contrast, Dekemper teaches an amorphous formulation of olanzapine prepared by a lyophilization process. Nowhere does Dekemper teach or suggest amorphous olanzapine preparable by a process comprising the step of melting one or more crystalline forms of olanzapine. Accordingly, Applicant respectfully requests that this rejection under § 102 be withdrawn.

*Claim rejections under 35 U.S.C § 102(b) or, in the alternative, under 35 U.S.C § 103(a)*

Claims 1-5, 10, 12-18, and 22-34 have been rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Eckman, International Patent Application Publication No. WO/2002/094236 ("Eckman"). As

discussed above, the Examiner has indicated that claims 6 and 7 would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims. Thus, solely to expedite prosecution and without appearing to agree with the Examiner's remarks, independent claim 1 has been rewritten as a product-by-process claim incorporating the process of claim 6, which comprises the step of melting one or more crystalline forms of olanzapine. By contrast, Eckman teaches an aerosol formulation of olanzapine prepared by a vaporization process. Nowhere does Eckman teach or suggest amorphous olanzapine preparable by a process comprising the step of melting one or more crystalline forms of olanzapine. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

#### *Claim objections*

Claims 6 and 7 have been objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 6 has been amended to delete the reference to claim 1. Claim 7 depends from claim 6 and should now be patentable. Accordingly, Applicant respectfully requests that the objection to claims 6 and 7 be withdrawn.

In view of the above Amendment and Remarks, Applicant believes the pending Application is in condition for allowance.

If additional fees are due, please charge our Deposit Account No. 23/2825, under Docket No. V0005.70102US00, from which the undersigned is authorized to draw.

Dated: October 8, 2010

Respectfully submitted,

By /C. Hunter Baker/  
C. Hunter Baker, M.D., Ph.D.  
Registration Number: 46,533  
WOLF, GREENFIELD & SACKS, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
617.646.8000